REMARKS

Claims 1, 7-9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47, 49-51 and 60-64 are pending in this application. The Office Action rejects claims 1, 7-9, 14, 15, 27-30, 35-38, 44-51 and 60-64, and withdraws claims 2, 13, 16, 17, 25, 26, 31-34, 39-43 and 52-59 from consideration. By this Amendment, claims 1, 7-9, 14 and 15 are amended and claims 2, 13, 16, 17, 25, 27, 31-35, 39, 43, 48 and 52-59 are canceled without prejudice. Support for the amended claims can be found in the original claims as filed. Thus, no new matter is added.

In addition, the specification is amended herein to replace the Sequence Listing. In the new Sequence Listing, SEQ ID NO: 46 has been added. SEQ ID NO: 46 is the sequence recited in claim 8, which starts at nucleotide 1 of SEQ ID NO: 9 and ends at nucleotide 223 of SEQ ID NO: 6. This sequence is a combination of nucleotides 1-1395 of SEQ ID NO: 9 followed by nucleotides 1-233 of SEQ ID NO: 6. A review of these two sequences clearly reveals that SEQ ID NO: 6 fits together with SEQ ID NO: 9 beginning at nucleotide 1396 of SEQ ID NO: 9. As a result, the addition of this sequence to the Sequence Listing does not introduce new matter.

The attached paper copy and computer-readable copy of the Sequence Listing are submitted in compliance with 37 C.F.R. §§1.821-1.825. The contents of the paper copy and the computer-readable copy of the Sequence Listing are the same.

Claims 1, 14 and 15 are amended to remove the non-elected (i.e., non-env) nucleotide sequences of SEQ ID NOs 4, 16, 21, 30 and 31. Claims 1, 7, 9, 14 and 15 are amended to change 50% to 70%, as recited in dependent claims 27, 35, 39, 44 and 48, which are canceled herein. Claim 8 is amended to clarify the claimed nucleotide sequence.

Entry of the amendments is proper under 37 CFR §1.116 since the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration (since the amendments

amplify issues previously discussed throughout prosecution); (c) satisfy a requirement of form asserted in the previous Office Action; (d) do not present any additional claims without canceling a corresponding number of finally rejected claims; and (e) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

Claims 2, 13, 16, 17, 25, 26, 31-34, 39-43 and 52-59 are withdrawn from consideration. Claims 2, 13, 16, 17, 25, 31-34, 39, 43 and 52-59 are canceled herein. Claims 40-42 depend from elected claim 9 and are directed to the env-gene. Therefore, these claims should not be withdrawn from consideration. Claim 26 is directed to a method for using the nucleotide fragment of elected claim 14. It is respectfully submitted that this claim should be rejoined when claim 14 is allowed.

I. Rejection under §112, second paragraph

The Office Action rejects claim 8 under 35 U.S.C. §112, second paragraph on the basis that reference to a gene beginning in one SEQ ID NO and ending in another SEQ ID NO is confusing. Amended claim 8 features a polynucleotide identified as SEQ ID NO: 46, as suggested by the Office Action. Claim 8 clearly identifies the nucleotide sequence and satisfies the requirements of section 112, second paragraph. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

II. Rejection under §112, first paragraph

The Office Action rejects claims 1, 7-9, 14, 15, 27-30, 35-38, 44-51 and 60-64 under 35 U.S.C. §112, first paragraph, alleging that the specification does not adequately support the claimed nucleic acids. The Office Action holds the position that the specification does not provide sufficient enough detail so that one skilled in the art can reasonably conclude that

the inventors had possession of the claimed nucleic acids. Applicants respectfully disagree with this position and traverse the rejection.

A. Initial burden on the PTO

The initial burden in on the PTO to establish that the claimed subject matter is not described by the specification. The PTO has not met that burden. While the absence of express support for the claims may provide a basis for a rejection under section 112, first paragraph, in this case, the specification does in fact expressly support the claims. The specification contains the exact words now claimed, for example, at pages 6-8. Thus, the specification does not fail to describe the claimed subject matter.

B. Possession of the invention

The Office Action seeks to limit the scope of the claims to only those particular clones containing SEQ ID NOs: 6, 9, and 12. However, there is no *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed. Describing the complete chemical structure (i.e., the DNA sequence) of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method. An adequate written description of a DNA "requires a precise definition, *such as*, by structure, formula, chemical name, or physical properties." Eli Lilly, 119 F.3d. 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997) (emphasis added).

As detailed in the Guidelines for Examination of Patent Applications Under 35 U.S.C. §112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 4, 1101 (Jan. 5, 2001) ("Guidelines"), an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or

structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics which permit a person skilled in the art to recognize that the applicant had possession of the claimed invention. (See Guidelines at 1104).

In this instance, Applicants disclose the isolation and characterization of the multiple sclerosis associated retrovirus MSRV-1, including details on the preparation, cloning and sequencing of various regions of the proviral DNA and genomic RNA. Applicants disclose the preparation of multiple clones from a variety of source materials. Also, Applicants describe the variation occurring within the clones.

Example 1 details the preparation and analysis of the "CL6-5'" and "CL6-3'" regions of the MSRV-1 genome, from total RNA extracted from human blood. Clones from these regions yielded the nucleotide and amino acid sequence information for the MSRV-1 envelope gene and protein represented by SEQ ID NO: 6 and SEQ ID NO: 7.

Example 2 details the preparation and analysis of the "C15" clone, encoding a portion of the MSRV-1 envelope, from total RNA extracted from concentrated virions from a synoviocyte culture. The C15 clone contained the env region represented by SEQ ID NO: 9 and SEQ ID NO: 10. From these clones, Applicants produced the complete envelope sequence, represented in Figure 13.

Example 3 details the preparation and analysis of the "5M6" clone, containing the 3' terminal region of the envelope gene presented by the MSRV-1 proviral DNA, from DNA extracted from immortalized B lymphocytes in culture from an MS patient. The 5M6 clone provided the nucleotide and amino acid sequences represented by SEQ ID NO: 12 and SEQ ID NO: 13.

Example 9 details the preparation and analysis of the "87-23" clone, corresponding to the pol/RT region, the integrase region, and 480 bp from the start of the env region, from RNA extracted from human blood.

Example 4 details the preparation and analysis of the LB16 clone, encoding at least the integrase protein, from RNA extracted from the choroid plexus of an MS patient. Example 5 details the preparation and analysis of the CL2 clone, containing at least portions homologous to the pol and gag genes. Example 7 details the preparation and analysis of the LB13 clone, containing at least the gag gene and a portion homologous to the U5 LTR region.

As disclosed in the specification, by the Examples, the Figures and the nucleotide and amino acid sequences, Applicants describe the substantial variation that occurs within the viral genes and between the viral sources. The sequence data disclosed from an array of clones reflects the variation within the genus. The description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. (See Guidelines, at 1106). As such, claims directed to polynucleotides and nucleic acids having 50%, 70%, 80%, 90% and/or 95% identity with the sequences of SEQ ID NOs: 6, 9 and 12 have adequate written description under 35 U.S.C. §112, first paragraph.

In addition, in an effort to expedite allowance, the independent claims have been amended to recite 70% identity rather than 50% identity. It is respectfully submitted that for the reasons discussed above the specification clearly provides written description for this higher percent identity.

Accordingly, for all of the above reasons, claims 1, 7-9, 14, 15, 27-30, 35-38, 44-51 and 60-64 satisfy the requirements of 35 U.S.C. §112, first paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 7-9, 14, 15, 26, 28-30, 36-38, 40-42, 45-47, 49-51 and 60-64 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

William P. Berridge
Registration No. 30,024

Melanie L. Mealy
Registration No. 40,085

WPB:MLM/jam

Attachments:
Sequence Listing (paper and computer-readable copies)

Date: March 24, 2004

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

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